



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,118	11/13/2003	Toshiyuki Takai	671302-2002	8301

20999 7590 10/11/2006  
FROMMER LAWRENCE & HAUG  
745 FIFTH AVENUE- 10TH FL.  
NEW YORK, NY 10151

EXAMINER

HAMA, JOANNE

ART UNIT PAPER NUMBER

1632

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/712,118

Applicant(s)

TAKAI ET AL.

Examiner

Joanne Hama, Ph.D.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,19 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant filed a response to the Final Rejection of June 16, 2006 on September 14, 2006. Upon further consideration, the Examiner withdraws finality of the Final Rejection and submits the following Non-Final Action.

Claims 1, 3, 4 are amended. Claim 2, 6-18 are cancelled.

Claims 1, 3-5, 19, 20 are under consideration.

It is noted that the amendment to the claims does not comply with 37 CFR 1.121(c). Applicant has indicated that claim 5 is "currently amended." However, there are no markings in claim 5 that indicate any changes. Applicant must comply with the rules set forth in MPEP 714, or risk non-entry of amendments.

### **Withdrawn Rejections**

#### **35 U.S.C. § 102(a/e)**

Applicant's arguments, see page 5-6 of Applicant's response, filed September 14, 2006, with respect to the rejection of 1, 3-5, 19, 20 have been fully considered and are persuasive. Applicant indicates that claim 1 has been amended to specify that the claimed mice comprise a homozygous disruption that includes the promoter region and exons 1, 2, and 3. The rejection of claims 1, 3-5, 19, 20 has been withdrawn.

### **New Rejection**

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1632

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-5, 19, 20 remain rejected in modified form under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

a transgenic mouse comprising a homozygous disruption of DAP12 (DNAX Activation Protein 12) in its genome, wherein the transgenic mouse exhibits hypomyelinosi of the thalamus, and wherein the mouse exhibits Nasu-Hakola disease, does not reasonably provide enablement for

a transgenic mouse comprising a homozygous disruption of DAP12 (DNAX Activation Protein 12) in its genome, wherein the transgenic mouse exhibits hypomyelinosi of the thalamus, and wherein the mouse exhibits a neuropsychiatric disorder selected from the group consisting of dementia, schizophrenia, schizotypal personality disorders, obsessive-compulsive disorder, or Tourette's syndrome.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for reasons of record, June 16, 2006 and December 30, 2005.

Upon further consideration, the scope of the claimed invention has been modified as follows. A response to Applicant's rebuttals, filed September 14, 2006 follows the rejection.

Regarding the scope of the claimed mice being limited to exhibiting Nasu-Hakola disease, neither the art nor the specification provides any guidance that the claimed

Art Unit: 1632

mice are models for the broad scope of neuropsychiatric disorders other than Nasu-Hakola. The issue here is similar to that of the enablement issues regarding the mice being a model of Huntington's disease. At the time of filing, the disorders of dementia, schizophrenia, schizotypal personality disorders, and obsessive-compulsive disorders, and Tourette's syndrome, are associated with many different neurological diseases which manifest these disorders. For example, the art teaches that patients who have diseases such as Pick's disease (Goedert et al., 1998, Neuron, 21: 955-958), Parkinson's disease (Emre, 2003, The Lancet, 2: 229-237), and HIV (Zink et al., 1999, FEMS Immunology and Medical Microbiology 26: 233-241) exhibit dementia, however, the etiology and pathology of dementia in Pick's disease, Parkinson's disease, and HIV are distinct from that of the dementia exhibited in Nasu-Hakola patients. In particular, Pick's disease patients exhibit frontotemporal dementia caused by Pick bodies that contain abnormal filaments, which consist of hyperphosphorylated tau (Goedert, page 955, 1<sup>st</sup> col., 1<sup>st</sup> parag.); in the case of Parkinson's disease, Emre teaches that in neocortical areas, a decrease in dopamine concentrations was greater in Parkinson's patients with dementia (Emre, page 231, 2<sup>nd</sup> col., parag. under "Dopaminergic deficits"); and in the case HIV, HIV encephalitis is the common pathologic correlate of HIV-dementia (Zink et al., abstract). In the case of the instant Application, the specification teaches that Nasu-Hakola patients is a central nervous system disorder caused by a mutation in the DAP12 (KARAP (Killer activating receptor associated protein)/TYROBP (protein tyrosine kinase binding protein) gene (specification, page 2, 2<sup>nd</sup> parag. under "Background of the Invention"). While the specification teaches that Nasu-Hakola

Art Unit: 1632

patients exhibit pre-senile dementia, the dementia in Nasu-Hakola patients have a different etiology and pathology than that of dementia in Pick's disease, Parkinson's disease, and HIV dementia. To indicate that the claimed mice exhibit "dementia" is broad and is not enabled because it would then imply that the claimed mouse is a model for other neurological diseases other than Nasu-Hakola. A similar argument regarding the scope of the symptoms, schizophrenia, schizotypal personality disorders, and obsessive-compulsive disorders and Tourette's syndrome can be made: the symptoms broadly encompass a variety of other diseases which manifest the symptoms. Nothing in the specification teaches that any of the symptoms exhibited in other diseases have the same etiology and pathology as that exhibited by the claimed mice and in Nasu-Hakola patients and thus, the claims are not enabled for its fullest breadth.

### ***Response to Arguments***

Applicant's arguments, see pages 3-4 of Applicant's response, filed September 14, 2006, with respect to the rejection of claims 1-5, 19, 20 have been fully considered and are persuasive. Applicant indicates that there were three outstanding issues with regard to the rejection of the claims under 35 U.S.C. § 112, 1<sup>st</sup> parag.

First, with regard to the issue of the scope of the oligodendrocyte disorder, i.e., hypomyelinos of the thalamus, Applicant has amended claim 1 to indicate that the transgenic mouse exhibits this phenotype. This amendment is found persuasive. As such, the rejection related to this issue is withdrawn.

Second, with regard to the enablement of the claimed mice exhibiting Huntington's disease, Applicant amended claim 4 to exclude Huntington's disease from the list of neuropsychiatric disorders. This amendment is found persuasive. As such, the rejection related to this issue is withdrawn.

Third, with regard to the enablement of the claimed mice encompassing heterozygous DAP12 mice, Applicant has amended claims 1 and 3 to indicate that the claimed mice exhibiting the phenotypes listed in claims 1 and 3 to be homozygous. This amendment is found persuasive. As such, the rejection related to this issue is withdrawn.

The rejection of claims 1-5, 19, 20 has been withdrawn. It is noted that the rejection of claim 2 is withdrawn as claim 2 is cancelled.

### ***Conclusion***

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1632

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JH

ANNE M. WEHBE PH.D  
PRIMARY EXAMINER

